

Patent Docket P1467R2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

<p>In re Application of Camellia W. Adams et al. Serial No.: 09/602,812 Filed: June 23, 2000 For: Humanized Anti-ErbB2 Antibodies and Treatment with Anti-ErbB2 Antibodies</p>	<p>Group Art Unit: 1642 Examiner: Anne Holleran</p> <div style="text-align: right; padding-right: 10px;"> <i>03 APR 28 2003</i> <i>RECEIVED APR 28 2003 USPTO</i> <i>W M Lee</i> Wendy M. Lee </div>
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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner of Patents
Washington, D.C. 20231



Sir:

Applicants submit herewith patents, publications or other information (attached hereto and listed on the attached revised Form PTO-1449) of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR §1.56.

This Information Disclosure Statement is filed in accordance with the provisions of:

37 CFR §1.97(b)

- within three months of the filing date of the application other than a continued prosecution application under 37 CFR §1.53(d); or
- within three months of the date of entry of the national stage of a PCT application as set forth in 37 CFR§1.491, or
- before the mailing of the first Office action on the merits; or
- before the mailing of the first Office action after the filing of a request for a continued examination under 37 CFR §1.114.

37 CFR §1.97(c)

- by the applicant after the period specified in 37 CFR §1.97(b), but prior to the mailing date of any of a final action under 37 CFR §1.113, or a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application, and is accompanied by either the fee set forth in 37 CFR §1.17(p) or a statement as specified in 37 CFR §1.97(e), as checked below.

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37 CFR §1.97(d)

- after the period specified in CFR § 1.97(c), and is accompanied by the fee set forth in 37 CFR §1.17(p) and a statement as specified in 37 CFR §1.97(e), as checked below.

{If either of boxes 37 CFR §1.97(c) or 37 CFR §1.97(d) is checked above, the following statement under 37 CFR §1.97(e) may need to be completed.}

37 CFR §1.97(e) Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.

37 CFR §1.704(d) Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and the communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of this information disclosure statement. Therefore, in accordance with the provisions of 37 CFR §1.704(d), the filing of this information disclosure statement will not be considered a failure to engage in reasonable efforts to conclude prosecution under 37 CFR §1.704.

The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p). Any deficiency or overpayment should be charged or credited to this deposit account.

A list of the patent(s) or publication(s) is set forth on the attached revised Form PTO-1449 (Modified).

A copy of the items on PTO-1449 is supplied herewith.

Those patent(s) or publication(s) which are marked with an asterisk (*) in the attached PTO-1449 form are not supplied.

BLAST results enclosed:

The undersigned also wishes to bring to the attention of the Examiner BLAST results of computerized alignments of the against sequences contained in the nucleotide and protein databases. The BLAST results are provided in paper form and are identified as reference "BLAST Results A-1- A-()" (nucleotide) and "BLAST Results B-1 - B-()" (protein) on the PTO Form 1449. Applicant requests that these references also be considered and that the Form 1449 be initialed to indicate the Examiner's consideration of the references.

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A concise explanation of relevance of the items listed on PTO-1449 is:

not given

given for each listed item

given for only non-English language listed item(s) [Required]

in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

In accordance with 37 CFR §1.97(g), the filing of this information disclosure statement shall not be construed as a representation that a search has been made.

In accordance with 37 CFR §1.97(h), the filing of this information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b).

The Commissioner is hereby authorized to charge any additional fees required under 37 CFR 1.16 and 1.17 for this Information Disclosure Statement, or credit overpayment to Deposit Account No. 07-0630. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

GENENTECH, INC.

Date: April 28, 2003

By: Wendy Lee
Wendy Lee
Reg. No. 40,378
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PATENT TRADEMARK OFFICE

FORM PTO-1449		U.S. Dept. of Commerce Patent and Trademark Office		Atty Docket No. P1467R2	Serial No. 09/602,812
LIST OF DISCLOSURES CITED BY APPLICANT (Use several sheets if necessary)				Applicant Adams et al.	
				Filing Date 23 Jun 2000	Group 1642

U.S. PATENT DOCUMENTS

Examiner Initials	Document Number	Date	Name	Class	Subclass	Filing Date
	236 2002/0076695	20.06.02	Ross, J.			
	237 2002/0155527	24.10.02	Stuart et al.			
	238 5,514,554	07.05.96	Bacus, S.			
	239 5,571,894	05.11.96	Wells, W. et al.			
	240 5,587,458	24.12.96	King, C. et al.			
	241 5,783,404	21.07.98	Koski, R.			
	242 5,846,749	08.12.98	Slamon et al.			
	243 5,856,089	05.01.99	Wang et al.			
	244 5,882,864	16.03.99	An et al.			
	245 5,925,519	20.07.99	Jensen et al.			
	246 5,994,071	30.11.99	Ross et al.			
	247 6,270,765	07.08.01	Deo et al.			
	248 6,333,348	25.12.01	Vogel et al.			
	249 6,358,682	19.03.02	Jaffee et al.			
	250 6,395,272	28.05.02	Deo et al.			
	251 6,403,630	11.06.02	Dannenberg et al.			
	252 6,458,356	01.10.02	Arakawa et al.			
	253 6,512,097	28.01.03	Marks et al.			

FOREIGN PATENT DOCUMENTS

Examiner Initials	Document Number	Date	Country	Class	Subclass	Translation Yes No
	254 1,006,194	07.06.00	EPO			
	255 412,116	29.11.95	EPO			
	256 444,181	31.10.01	EPO			
	257 494,135	10.04.96	EPO			
	258 502,812	14.08.96	EPO			
	259 554,441	27.01.99	EPO			
	260 656,367	07.06.95	EPO			
	261 WO 01/05425	25.01.01	PCT			
	262 WO 01/09187	08.02.01	PCT			
	263 WO 01/20033	22.03.01	PCT			
	264 WO 01/21192	29.03.01	PCT			
	265 WO 01/32155	10.05.01	PCT			
	266 WO 87/07646	17.12.87	PCT			
	267 WO 89/10412	02.11.89	PCT			
	268 WO 91/02062	21.02.91	PCT			

Examiner	Date Considered
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	269 WO 91/05264	18.04.91	PCT				
	270 WO 93/03741	04.03.93	PCT				
	271 WO 93/16185	19.08.93	PCT				
	272 WO 96/07321	14.03.96	PCT				
	273 WO 96/16673	06.06.96	PCT				
	274 WO 96/40789	19.12.96	PCT				
	275 WO 97/00271	03.01.97	PCT				
	276 WO 98/02463	22.01.98	PCT				
	277 WO 98/16628	23.04.98	PCT				
	278 WO 98/18489	07.05.98	PCT				
	279 WO 98/33914	06.08.98	PCT				
	280 WO 99/55367	04.11.99	PCT				

OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

281	Agus at al., "Differential Anti-Tumor Effects of Targeting Distinct Epitopes of the Her-2/neu Extracellular Domain in Xenograft Models of Prostate Cancer." <u>Proceedings of the American Association for Cancer Research Annual Meeting</u> (Abstract #4570) 41:719 (Mar 2000)
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283	American Cancer Society Textbook of Clinical Oncology, Murphy et al., 2nd edition, Atlanta:American Cancer Society pps. 126-127 (1995)
284	Ching, K., "Role of c-erb B gene family in prostate cancer" <u>Dissertation Abstracts International</u> 55(11):4738-B (May 1995)
285	Curnow, R., "Clinical experience with CO64-directed immunotherapy. An overview" <u>Cancer Immunology and Immunotherapy</u> 45(3-4):210-215 (Nov-Dec 1997)
286	Curti, B., "Physical barriers to drug delivery in tumors" <u>Critical Reviews in Oncology-Hematology</u> 14(1):29-39 (Feb 1993)
287	Ezeh et al., "Differential activation of ErbB receptors in the rat olfactory mucosa by transforming growth factor- α and epidermal growth factor in vivo" <u>Journal of Neurobiology</u> 37(2):199-210 (Nov 5, 1998)
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289	Gura, T., "Systems for identifying new drugs are often faulty" <u>Science</u> 278(5340):1041-1042 (Nov 7, 1997)
290	Held et al., "Real time quantitative PCR" <u>Genome Research</u> 6(10):986-994 (1996)
291	Jain, R., "Barriers to drug delivery in solid tumors" <u>Scientific American</u> 271(1):58-65 (JUL 1994)
292	James et al., "Phase II Trial of the Bispecific Antibody MDX-H210 (anti-Her2/Neu X anti-CD64) Combined With GM-CSF in Patients With Advanced Prostate and Renal Cell Carcinoma That Express Her2/Neu." <u>British Journal of Cancer</u> (Abstract #56) 78:19 (1998)

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USCOMM-DC 80-398.

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OTHER DISCLOSURES (Including Author Title, Date, Pertinent Pages, etc.)				
293	James et al., "Phase II trial of the bispecific antibody MDX-H210 (anti-HER2/NEU X anti-CD54) combined with GM-CSF in patients with advanced prostate and renal cell carcinomas that express HER2/NEU" <u>Proc. Annu. Meet. Soc. Clin. Oncol.</u> (Abstract No. 1681) 17:436a (1998)			
*294	Kabat. <u>Sequences of Proteins of Immunological Interest</u> . US Dept of Health and Human Services, NIH, 5th edition, Bethesda, MD (1991)			
295	Knox et al., "Yttrium-90-labeled anti-CD20 monoclonal antibody therapy of recurrent B-cell lymphoma" <u>Clinical Cancer Research</u> 2(3):457-470 (Mar 1996)			
296	Medarex, Inc., "Medarex's HER-2 product show anti-cancer effects in phase II prostate and kidney studies" (company press release) (May 19, 1998)			
297	Myers et al., "Intracellular antibody mediated down-regulation of p185 erbB-2 expression in malignant prostatic cells" <u>Proceedings of the American Association for Cancer Research Annual Meeting</u> (Abstract #2334) 37:342 (1996)			
298	Nagabhushan et al., "CWR22: The First Human Prostate Cancer Xenograft with Strongly Androgen-dependent and Relapsed Strains Both in Vivo and in Soft Agar" <u>Cancer Research</u> 56:3042-3046 (1996)			
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300	Okabayashi et al., "Podofilox-induced regression of Shope papillomas may be independent of host immunity" <u>Journal of Investigative Dermatology</u> 101(6):852-857 (Dec 1993)			
301	Okuda et al., "The cytostome of Trypanosoma cruzi epimastigotes is associated with the flagellar complex" <u>Experimental Parasitology</u> 92(4):223-231 (Aug 1999)			
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303	Skrepnik et al., "Recombinant Oncoxin AR109 (anti-p185erbB-2) Diminishes Human Prostate Carcinoma Xenografts" <u>Journal of Urology</u> 161:984-989 (1999)			
304	Stearns et al., "Workgroup 2: Human Xenograft Models of Prostate Cancer" <u>Prostate</u> 36:56-58 (1998)			
305	Wainstein et al., "CWR22: Androgen-dependent Xenograft Model Derived from a Primary Human Prostatic Carcinoma" <u>Cancer Research</u> 54:6049-6052 (1994)			
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Examiner	Anne L. Kullman	Date Considered	11/19/03
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Examiner

Mary L. Hellerman

Date Considered

(1/1/03)

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